

CHAPTER 202
CERTIFICATE OF NEED PROGRAM
[Prior to 7/29/87, Health Department[470] Ch 202]

641—202.1(135) Definitions. For purposes of this chapter, the following definitions apply:

“Acute care category of bed usage,” as the term applies in Iowa Code section 135.63(2) *“k,”* shall be the same as the acute care categories listed in the state survey section of the American Hospital Association Annual Survey of Hospitals.

“Any expenditure in excess of five hundred thousand dollars,” as defined in Iowa Code section 135.61(18) *“e,”* means new capital expenditures and new personnel necessary to operate the service for a year.

“Any mobile health service with a value in excess of one million five hundred thousand dollars,” as defined in Iowa Code section 135.61(18) *“l,”* means the value of all equipment used to provide the service, including the trailer. The party providing the equipment shall be the applicant regardless of the location of that party.

“Appropriate geographic service area,” as the term applies to defining affected persons in Iowa Code section 135.61(1) *“c,”* shall be defined as follows:

1. For applications regarding hospitals, hospitals located in the same county and in Iowa counties contiguous to the county wherein the applicant hospital’s proposed project will be located.

2. For applications regarding health care facilities, other health care facilities located in the same county and in Iowa counties contiguous to the county wherein the applicant’s proposed health care facility will be located.

3. For applications sponsored by other than the hospitals or health care facilities specified in paragraphs “1” and “2,” those providers within the same county who offer similar service or might logically be viewed as potential providers of such service.

“Bed capacity” shall be defined as follows:

1. For hospitals, bed capacity is defined as the total facility licensed beds as reported on the state survey section of the American Hospital Association Annual Survey of Hospitals.

2. For health care facilities, bed capacity is defined as a facility’s licensed bed capacity according to the department of inspections and appeals.

“Cardiac catheterization service,” as the term applies to a new or changed institutional health service in Iowa Code section 135.61(18) *“m”(1),* means the initiation or expansion of this service.

“Consumers served by a new institutional health service” means those consumers residing in the service area as determined by the department.

“Long-term (acute) care hospital,” for purposes of these rules, means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a long-term care hospital-prospective payment system hospital (LTCH-PPS) in accordance with 42 CFR Part 412.

“Open heart surgical service,” as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) *“m”(2),* means the initiation or expansion of this service.

“Organized outpatient health facility,” as defined in Iowa Code section 135.61(20), shall include, but not be limited to, the following types of facilities:

1. Community mental health centers; and
2. Comprehensive outpatient rehabilitation facilities (CORFs) certified by Medicare.

“Organ transplantation service,” as the term applies to a new or changed institutional health service in Iowa Code section 135.61(18) *“m”(3),* means the initiation or expansion of this service. Each type of organ transplant shall be considered separately.

“Permanent change in bed capacity of an institutional health facility” means a change which is intended to be effective for one year or more.

1. A conversion of a long-term acute care hospital or a rehabilitation hospital as defined by federal regulations to a general acute care hospital or to a different type of specialty hospital is a permanent change in bed capacity and requires a certificate of need.

2. A hospital which has deleted beds pursuant to Iowa Code section 135.63(2) “g” for the purpose of receiving designation as a critical access hospital may reestablish the deleted beds at a later time without obtaining a certificate of need, provided that the number of beds reestablished does not exceed the number of beds maintained prior to the deletion as reported on the bed reduction form.

“*Physical facility*,” as the term applies in Iowa Code section 135.61(18) “f,” means a separately licensed facility.

“*Private offices and private clinics of an individual physician, dentist, or other practitioner or group of health care providers*.” The meaning of this term as used in Iowa Code section 135.63(2) “a” shall be determined by looking at factors which include, but are not limited to:

1. The type of health care service delivered;
2. The control and supervision of medical judgment in the care of and treatment of patients;
3. The control and supervision of professional assistants, including nurses, physician assistants, and technicians; and
4. The ownership and maintenance of medical records of patients.

“*Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment*,” as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) “m”(4), means the initiation or expansion of this service.

“*Rehabilitation hospital*,” for the purposes of these rules, means a hospital that has been approved to participate in the Title XVIII (Medicare) program as an inpatient rehabilitation facility-prospective payment system hospital (IRF-PPS) in accordance with 42 CFR Part 412.23(b), 412.25 or 412.29.

“*Relocation of an institutional health facility*,” as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) “b,” means the replacement of a facility located in one county with a facility located in another county.

“*Value in excess of one million five hundred thousand dollars*,” as used in Iowa Code section 135.61(18) “g,” “h,” “i” and “j,” means the value of the equipment including any applicable sales tax, delivery charge and installation charge.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.2(135) Letter of intent.

202.2(1) Before applying for a certificate of need, the sponsor of a proposed new institutional health service or changed institutional health service shall submit a letter of intent to the department. The letter of intent shall contain the following:

- a. A brief description of the proposed project;
- b. The project’s location;
- c. The project’s estimated cost (site costs, land improvements, facility costs, movable equipment and financing costs); and
- d. An explanation of how the project will be financed.

202.2(2) The letter shall be submitted as soon as possible after the initiation of the applicant’s planning process and in any case not less than 30 calendar days before applying for a certificate of need and before substantial expenditures are made. This 30-day waiting period shall begin upon the department’s receipt of the applicant’s letter of intent.

202.2(3) The department shall make available on the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us, all criteria and standards which are pertinent to an application.

202.2(4) A letter of intent received by the department shall be valid for a period of one year from the date of receipt by the department. The sponsor may renew the validity of a letter of intent by providing written notification to the department prior to the one-year expiration date.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.3(135) Determination of reviewability. A sponsor of a proposed project may submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

202.3(1) The request should include sufficient details of the proposed project and cite the sections of the Iowa Code that the sponsor relies upon to assert the project is not reviewable.

202.3(2) Upon receipt of a written request from the sponsor of a project, the department shall determine if a proposed project requires a certificate of need under Iowa Code sections 135.61 to 135.83. The department may request additional information about the project to make the determination.

a. If it is determined that a certificate of need is required, the sponsor shall be notified by the department and the request for nonreviewability shall be considered the letter of intent for purposes of subrule 202.2(2).

b. If it is determined that a certificate of need is not required, the sponsor shall be notified by the department and the determination of nonreviewability shall be placed on the next agenda of the state health facilities council for consideration.

c. The notification to the sponsor of the results of the department's review of the request shall include specific Iowa Code citations relied upon to support the determination.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.4(135) Submission of application.

202.4(1) Application form.

a. A sponsor of a proposed project for a new or changed institutional health service shall submit to the department an application for certificate of need by using the appropriate application form found on the certificate of need Web page located on the department's Web site, www.idph.state.ia.us. All information requested in the application form will be required in the absence of a waiver by the department.

b. An original application and six copies thereof shall be sent to the Certificate of Need Program, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. An electronic copy of the application and all attachments shall also be submitted.

c. The department shall establish and maintain files on each application.

202.4(2) Application fee. The application shall be accompanied by a fee equivalent to three-tenths of 1 percent of the anticipated cost of the project. There shall be a minimum fee of \$600 and a maximum fee of \$21,000.

a. The fee shall be based on the total cost of the project, which shall include site costs, land improvements, facility costs, movable equipment and financing costs.

b. The fee for leased or donated new institutional health services shall be calculated in the same manner as if the new institutional health services were purchased.

(1) The leased equipment fee shall be based on total value of the lease, plus sales tax, delivery and installation.

(2) The lease of space includes the cost of a one-year-lease payment for the space in addition to other costs associated with the project.

(3) Financing costs shall not be applicable on leases or cash purchases.

c. The fee shall be remitted by check made payable to the Treasurer, State of Iowa, and addressed to Iowa Department of Public Health—Certificate of Need, Lucas State Office Building, Des Moines, Iowa 50319-0075.

d. The application fee will be refunded by the department for any application which is voluntarily withdrawn from the review process in the following amounts:

(1) If an application is voluntarily withdrawn within 30 calendar days after submission, 75 percent of the fee shall be refunded;

(2) If an application is voluntarily withdrawn more than 30 but within 60 calendar days after submission, 50 percent of the fee shall be refunded;

(3) If an application is withdrawn voluntarily more than 60 calendar days after submission, 25 percent of the application fee shall be refunded.

e. The department shall refund the proper amount within 30 calendar days of the applicant's voluntary withdrawal.

f. An applicant for a new or changed institutional health service offered or developed by an intermediate care facility for persons with an intellectual disability or for persons with a mental illness is exempt from payment of the application fee.

g. For purposes of this subrule and Iowa Code section 135.63(1), the term “submission” shall mean the day the application is received by the department.

202.4(3) Determination of completeness.

a. The department shall send written notice to the applicant within 15 business days of receipt of the application if the application has been accepted as complete or otherwise state in said notice what information is needed to make the application complete.

b. An application shall be deemed “accepted” once the department has determined it to be complete and the fees defined in 202.4(2) “*a*” are paid in full.

202.4(4) Promptly after an application is accepted, the department shall provide written notification to all affected persons defined in Iowa Code section 135.61(1) “*c*” and “*d*” which are identified on the department of inspections and appeals Web site or by the applicant, as provided in Iowa Code section 135.66(2). The department shall notify other affected persons by posting such notification to the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us. The notice and the Web page shall identify deadlines for the submission of written materials as provided in 202.6(2).

202.4(5) Written analysis of application.

a. The department shall provide a written report evaluating the application against all applicable criteria specified in Iowa Code section 135.64.

b. All reports shall be provided to council members and to the applicant prior to the health facilities’ council meeting at which the application is to be heard.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.5(135) Organizational procedures.

202.5(1) The presence of four members of the council shall constitute a quorum.

202.5(2) The chairperson and all other council members present shall cast votes or abstain, as the case may be, on all council action. No proxy votes shall be allowed.

202.5(3) A vote of a majority of those present shall be necessary to take action on any motion before the council. A tie vote shall mean no action on the motion.

202.5(4) The council shall, at the first meeting after July 1 of each odd-numbered year, elect a vice-chairperson, who shall perform the duties of the chairperson in the absence of the chairperson, when the chairperson has a conflict of interest or when the chairperson so directs.

202.5(5) The department shall notify the public and affected parties of the council meeting agenda utilizing the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us.

202.5(6) A council member shall refrain from participating in an application review process if the member:

- a.* Has a personal bias or prejudice concerning the applicant;
- b.* Has acted as counsel to the applicant or a competitor of the applicant in the same or adjoining county within the past two years;
- c.* Has a financial interest in the outcome of the application process or any other significant personal interest that could be substantially affected by the outcome of the case;
- d.* Has a spouse or relative within the third degree of relationship that (1) is affiliated with or represents the applicant or a competitor of the applicant in the same or adjoining county; (2) has a known financial or significant personal interest which could be substantially affected by the outcome of the application process; or (3) is likely to testify on behalf of the applicant or an affected person at public hearing; or
- e.* Has any other legally sufficient cause to refrain from participating in the application review process.

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641—202.6(135) Public hearing on application. Public hearings conducted pursuant to Iowa Code section 135.66(3) “b” are not contested cases. Judicial review pursuant to Iowa Code section 17A.19 of final agency decisions under Iowa Code section 135.69 shall be treated as other agency action.

202.6(1) The council shall use the following meeting format:

- a. Announcement of application under review.
- b. Presentation of department report.
- c. Applicant presentation.
- d. Affected persons’ presentation.
- e. Applicant’s rebuttal.
- f. Council discussion, motion and final decision.

202.6(2) The notice of an accepted application issued pursuant to Iowa Code section 135.66(2) shall inform the applicant and affected persons of the deadlines for the submission to the department of written statements or other materials. These deadlines will also be posted on the certificate of need Web page on the department’s Web site, www.idph.state.ia.us.

a. Written submissions received by the department after the deadlines established in this notice shall not be considered by the department or the council unless submitted at the public hearing solely to support oral testimony or upon a showing of good cause.

b. Applicants and affected persons shall submit all written materials electronically. If electronic submission is not possible, then an original and six copies must be submitted.

202.6(3) The applicant, affected persons, or their designated representatives shall be given the opportunity to make oral presentations to the council. Other interested persons may be given the opportunity to make oral presentations to the council.

202.6(4) Oral testimony that simply duplicates material received in writing will not be heard. The applicant and affected persons shall present only one witness for each issue raised unless permission is requested and granted by the chairperson.

202.6(5) All questions to an applicant or affected person presenting oral testimony shall be directed from the council or council staff unless permission is requested and granted by the chairperson. Persons making oral presentations to the council are not expected to be placed under oath.

202.6(6) The council may designate technical consultants or experts to assist in its activities as defined by the council.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.7(135) Summary review. Pursuant to Iowa Code section 135.67, an applicant requesting a summary review shall abide by the following procedures:

202.7(1) If an applicant desires to request a summary review of its application for a certificate of need, it shall submit a written request for summary review, an original application and six copies thereof to the Certificate of Need Program, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. An electronic copy of the application and all attachments shall also be submitted. The applicant is not required to submit a letter of intent pursuant to Iowa Code section 135.65 prior to submitting a written request for a summary review.

202.7(2) The eligibility of an application for summary review pursuant to Iowa Code section 135.67 shall not mandate or require such review. The department will make the decision as to whether an application will be reviewed in the summary review process.

202.7(3) Upon receipt of a written request for summary review, an application, and the fee required by 202.3(2) “a,” the department shall notify the applicant in writing within 15 calendar days if the application is complete and if a summary review will be granted.

202.7(4) If an application is deemed incomplete, the department shall state specifically in writing what information is needed to make the application complete.

202.7(5) If the department notifies the applicant that a summary review will not be performed, this decision is binding on the applicant and the application will be entered into the formal review process on the date of written notice that such application will not be reviewed summarily.

202.7(6) A summary review of an application for a certificate of need shall be completed within 60 calendar days of the acceptance of an application by the department.

202.7(7) At any time during the summary review process, an application may be withdrawn without prejudice from the process. The applicant may then submit the application for a formal 90-day review. [ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.8(135) Extension of review time.

202.8(1) A formal review of an application for a certificate of need pursuant to Iowa Code section 135.66 may be extended by the department on the basis of any of the following criteria:

- a. In order to review competing applications simultaneously;
- b. In the case of technologically innovative equipment, to obtain additional information necessary to evaluate the proposal. The department shall specify in writing such additional information as necessary;
- c. At the request of the applicant;
- d. At the request of at least two members of the state health facilities council in order to allow additional time for deliberation on all evidence present. The council shall specify the time of the delay and the date on which the final decision will be rendered.

202.8(2) An extension by the department made pursuant to subrule 202.8(1) shall in no case be more than 60 calendar days beyond the time a decision is required under Iowa Code section 135.69 unless the applicant and department agree.

202.8(3) Where none of the provisions of 202.8(1) are applicable and where an application will be automatically denied because of the expiration of time required by Iowa Code section 135.69 for the issuance of a written decision by the council, the department shall notify the applicant of the likelihood of an automatic denial and shall ask the applicant to request in writing an extension of the review time. Where an extension is so requested, the application shall be heard at the next regularly scheduled meeting of the council or at any time agreeable to the applicant and the department.

641—202.9(135) Rehearing of certificate of need decision.

202.9(1) The applicant or any affected person who has participated or sought unsuccessfully to participate in the formal review procedure prescribed in Iowa Code section 135.66 may, for good cause shown, file an application for rehearing in writing with the department stating the specific grounds therefor and the relief sought, within 20 calendar days after the date of the issuance of the final decision on an application for certificate of need.

202.9(2) Grounds for rehearing include, but are not limited to:

- a. New significant, relevant information which was unavailable at the date of the hearing;
- b. Significant changes in factors or circumstances relied upon by the council in reaching its decision;
- c. Demonstration that the council has materially failed to follow its adopted procedures in reaching its decision; or
- d. Such other bases as the council determines constitute good cause.

202.9(3) An application for rehearing shall be deemed to have been denied unless the council grants the application in writing within 20 calendar days after its filing.

202.9(4) If the application for rehearing is granted, the council may issue an order modifying the initial final order, or may set the matter for consideration at a subsequent meeting date. If public hearing is granted on the application for rehearing, notice shall be provided ten calendar days prior to hearing to the person applying for rehearing, the applicant and other affected persons upon request pursuant to 202.10(135).

202.9(5) The council shall issue the final decision on rehearing, stating the basis for its decision, within 30 calendar days after the application for rehearing was granted or 30 calendar days after public hearing on rehearing, whichever is later.

202.9(6) If a rehearing is not requested or an affected party remains dissatisfied after the request for rehearing, an appeal may be taken in the manner provided by Iowa Code chapter 17A. A request for rehearing is not required prior to appeal under Iowa Code section 17A.19.

641—202.10(135) Status reports to affected persons. Affected persons are entitled to status reports from the department while a formal application review is in progress pursuant to Iowa Code section 135.68. The department shall maintain a log of all requests for written status reports by affected persons. Affected persons who request written status reports must submit their name and address in a written request (by letter, fax, or E-mail) to the department, identifying the specific information requested, which may include notification of the council's final decision, any application for rehearing, or the filing of a petition for judicial review. The formal process does not preclude informal contacts with department staff for verbal status reports. Copies of the council's final decision, an application for rehearing, a petition for judicial review, or any other public record will be provided upon request and payment of the department's per page fee for copies as described in 641—175.3(7).

641—202.11(135) Finality. The certificate of need application process is continuous beginning with submission of a letter of intent or request for waiver of a letter of intent through issuance of a final decision by the council subject to judicial review under Iowa Code chapter 17A.

202.11(1) The following stages of the process are intermediate and subject to judicial review only to the extent they meet criteria for intermediate review under Iowa Code section 17A.19.

a. A decision by the department pursuant to 641—202.3(135) that a proposed project does not require a certificate of need;

b. A decision by the department to waive submission of the letter of intent and substitute summary review; and

c. The rejection of an application by the department which fails to provide all information required under Iowa Code section 135.63, subsection 1.

202.11(2) The following stages of the process are final decisions subject to judicial review as final agency action under Iowa Code section 17A.19:

a. A decision by the department to disallow summary review;

b. A decision by the council that a proposed project does not require a certificate of need;

c. A decision by the council to approve or deny an application;

d. The council's final ruling on an application for rehearing; and

e. A decision by the council to revoke a certificate of need pursuant to 641—202.13(135).

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.12(135) Project progress reports. The department shall maintain an effective follow-up program to ensure that applicants make timely progress on each approved application.

202.12(1) The sponsor of an approved application shall submit a progress report using the form available on the certificate of need Web page on the department's Web site, www.idph.state.ia.us, to the department six months after approval at hearing.

202.12(2) Progress reports shall fully identify the project and indicate the current status of the project in descriptive terms. The reports shall also reflect an amended project schedule if necessary.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.13(135) Request for extension of certificate.

202.13(1) A request by the applicant for an extension of a certificate of need must be filed with the department using the form available on the certificate of need Web page on the department's Web site, www.idph.state.ia.us, no later than 30 days prior to the expiration of the certificate of need.

202.13(2) A request for extension shall fully identify the project and indicate the current status of the project in descriptive terms.

202.13(3) Any affected persons shall have the right to submit to the department in writing, or orally at the council meeting at which the extension request is considered, information which may be relevant to the question of granting an extension.

202.13(4) When an extension has been requested, the council shall approve or deny the request at a meeting of the council preceding the expiration of the certification. The certificate of need may be revoked by the council at the end of the certification period for insufficient progress in developing the project.

202.13(5) If the extension is denied, the applicant shall have the right to appeal under the provisions of Iowa Code section 135.70.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

641—202.14(135) Application changes after approval.

202.14(1) Once a project has been approved by the council, no changes that vary from or alter the number of approved beds, the approved services or the approved cost by an amount indicated in 202.14(2) shall be made unless requested by the applicant and approved by the council. Requests shall be made in writing and filed with the department.

202.14(2) An increase in the actual cost of the project over and above that originally approved shall automatically generate a rereview by the council if the increase exceeds the originally approved amount by:

- a. Fifteen percent for projects up to \$999,999.99;
- b. Twelve percent for projects from \$1,000,000.00 to \$4,999,999.99;
- c. Eight percent for projects \$5,000,000.00 and over.

An increase in the approved cost that falls below the above percentages shall be reported to the department.

202.14(3) Failure to notify and receive permission of the council to change the project as originally approved may result in the imposition of sanctions provided in Iowa Code section 135.73. The council may make a recommendation to the department regarding the imposition of a sanction and the amount of the fine to be imposed.

641—202.15(135) Sanctions. Hearings to determine class I or class II violations pursuant to Iowa Code section 135.73 shall be conducted in accordance with the department's procedural rules for contested cases found at 641—Chapter 173.

641—202.16(135) Reporting requirements. For the purposes of the annual reports and data compilation required in Iowa Code sections 135.75 and 135.78, the department will utilize the AHA Annual Survey of Hospitals with the state survey addendum for hospitals and the cost reports for health care facilities submitted to the Medicaid enterprise of the department of human services.

[ARC 1748C, IAB 12/10/14, effective 1/14/15]

These rules are intended to implement Iowa Code sections 135.61 to 135.79 and 135.83.

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◇ Two or more ARCs